Package leaflet: information for the user

Prismasol 2 mmol/l Potassium Solution for haemodialysis/haemofiltration

Calcium chloride dihydrate/ magnesium chloride hexahydrate/ glucose monohydrate/ lactic acid solution 90% w/w / sodium chloride/ potassium chloride/ sodium hydrogen carbonate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Prismasol is and what it is used for

Prismasol contains the active substances calcium chloride dihydrate, magnesium chloride hexahydrate, glucose monohydrate, lactic acid solution 90% w/w, sodium chloride, potassium chloride and sodium hydrogen carbonate.

Prismasol is used in the treatment of renal failure as a solution for continuous haemofiltration or haemodiafiltration (as a replacement for fluid lost from the blood passing through a filter) and continuous haemodialysis or haemodiafiltration (the blood flows on one side of a dialysis membrane while a haemodialysis solution flows on the other side of the membrane).

Prismasol solution may also be used in case of drug poisoning with dialysable or filterable substances.

Prismasol 2 mmol/l Potassium is indicated particularly in patients who have tendency to hyperkalaemia (a high concentration of potassium in the blood).

2. What you need to know before you use Prismasol

Do not use Prismasol 2 mmol/l Potassium in case of:

- allergy to one of the active substances or any of the other ingredients (listed in section 6),
- a low concentration of potassium in your blood (hypokalaemia),
- a high concentration of bicarbonate in the blood (metabolic alkalosis).

Presence of corn antigen in Prismasol cannot be excluded.

Do not use haemofiltration/ dialysis in the following cases:

- Renal failure with pronounced hypercatabolism (abnormally increased catabolism), if the uraemic symptoms (symptoms caused by high concentration of urea in your blood) cannot be corrected with haemofiltration,
- Insufficient arterial pressure in the vascular access,
- Systemic anticoagulation (reduced clotting of your blood), if there is a high risk of haemorrhage (bleeding).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Prismasol.
The solution should be used only by, or under the direction of a doctor competent in renal failure treatments using haemofiltration, haemodiafiltration and continuous haemodialysis.

Before and during treatment, your blood condition will be checked, e.g. your acid-base balance and concentrations of electrolytes (salts in the blood) will be monitored, including all fluid you are given (intravenous infusion) and that you produce (urine production), even those not directly related to the therapy.
Your blood glucose concentration should be closely monitored, especially if you are diabetic.

Other medicines and Prismasol
Tell your doctor or pharmacist if you are given, have recently been given or might be given any other medicines.
The blood concentration of some of your other medicines may be reduced during the treatment. Your doctor will decide if your medication should be changed.

In particular tell your doctor if you are using either of the following:
- Digitalis medicine (for treatment of certain heart conditions) as the risk of cardiac arrhythmia (irregular or rapid beating of the heart) caused by digitalis is increased during hypokalaemia (low concentration of potassium in your blood).
- Vitamin D and medicinal products containing calcium, as they can increase the risk of hypercalcaemia (a high concentration of calcium in your blood).
- Any addition of sodium hydrogen carbonate (or other buffer source) may increase the risk of metabolic alkalosis (excess of bicarbonate in your blood).
- When citrate is used as an anticoagulant (as a protective additive in dialysis equipment), it can reduce plasma calcium levels.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if you should be given Prismasol if you are pregnant or breast-feeding.

Driving and using machines
Prismasol is not known to affect the ability to drive or use machines.

3. How to use Prismasol

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The volume of Prismasol used will depend on your clinical condition and the target fluid balance. The dose volume is therefore at the discretion of the responsible doctor.

Administration route: Intravenous use and for haemodialysis.

If you think you use more Prismasol than you should
Your fluid balance, electrolyte and acid-base balance will be carefully monitored.
In the unlikely event that an overdose occurs, your doctor will take necessary corrective measures and adjust your dose.
Overdose may result in:
- fluid overload in your blood,
- elevation of the bicarbonate blood level (metabolic alkalosis),

and/or reduction of levels of salts in the blood (hypophosphataemia, hypokalaemia).
Overdose could lead to severe consequences, such as congestive heart failure, electrolyte or acid-base disturbances.

For instructions for use, please see section “The following information is intended for healthcare

professionals only".

If you have any further questions on the use of this medicine, please ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

Not known: frequency cannot be estimated from the available data

- Changes of levels of salts in the blood (electrolyte imbalances such as hypophosphataemia, hypokalaemia)
- Elevation of the plasma bicarbonate concentration (metabolic alkalosis) or reduction of the plasma bicarbonate concentration (metabolic acidosis)
- Abnormally high or low volume of water in the body (hyper or hypovolemia)
- Abnormally high concentration of glucose in the blood (hyperglycaemia)
- Nausea
- Vomiting
- Muscle cramps
- Hypotension (low blood pressure).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via:

Malta:
ADR Reporting Website:
www.medicinesauthority.gov.mt/adrportal

Republic of Ireland:
HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

United Kingdom:
Yellow Card Scheme
www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prismasol

Keep this medicine out of the sight and reach of children.
Do not store below +4°C.
Do not use this medicine after the expiry date which is stated on the label and the packaging. The expiry date refers to the last day of that month.
Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 24 hours at +22° C. If not used immediately in-use storage times and conditions prior to use are the responsibility of the user and shall not be longer than 24 hours including the duration of the treatment.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prismasol contains

The active substances are:

Before reconstitution:
1000 ml of electrolyte solution (from the small compartment (A)) contains

Calcium chloride dihydrate	5.145 g
Magnesium chloride hexahydrate	2.033 g
Glucose	22.000 g
(S)-Lactic acid	5.400 g

1000 ml of buffer solution (from the large compartment (B)) contains

Sodium chloride	6.450 g
Sodium hydrogen carbonate	3.090 g
Potassium chloride	0.157 g

After reconstitution:
The solutions in the compartments A (250 ml) and B (4750 ml) are mixed to give one reconstituted solution (5000 ml) of which the composition is:

		mmol/l	**mEq/l**
Calcium	Ca^{2+}	1.75	3.50
Magnesium	Mg^{2+}	0.50	1.00
Sodium	Na^{+}	140.00	140.00
Chloride	Cl^{-}	111.50	111.50
Lactate		3.00	3.00
Hydrogen carbonate	HCO_3^{-}	32.00	32.00
Potassium	K^{+}	2.00	2.00
Glucose		6.10	
Theoretical Osmolarity:		297 mOsm/l	

The other ingredients are: carbon dioxide (E 290), water for injections
pH of the reconstituted solution: 7.0–8.5

What Prismasol looks like and contents of the pack

Prismasol is presented in a two-compartment bag containing in the smaller compartment A, the electrolyte solution, and in the larger compartment B, the buffer solution. The final reconstituted solution is obtained after breaking the frangible pin and mixing both solutions. The reconstituted solution is clear and slightly yellow. Each bag (A+B) contains 5000 ml solution for haemofiltration and haemodialysis. The bag is overwrapped with a transparent film.
Each box contains two bags and a package leaflet.

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This leaflet was last revised in 12/2020

The following information is intended for healthcare professionals only:

Prismasol 2 mmol/l Potassium Solution for haemodialysis/haemofiltration

Precautions:
The instructions for use / handling for Prismasol must be strictly followed.

The solutions in the two compartments **must be mixed before use**.
Use of contaminated haemofiltration and haemodialysis solution may cause sepsis, shock and fatal conditions.

Prismasol may be warmed to 37°C to enhance patient comfort. Warming of the solution prior to use should be done before reconstitution with dry heat only. Solutions should not be heated in water or in a microwave oven. The solution should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact.

The solution is a potassium-containing solution. The serum potassium concentration must be monitored before and during haemofiltration and/or haemodialysis. Depending on the serum potassium concentration before treatment, hypo- or hyperkalaemia may develop.
If hypokalaemia occurs, addition of potassium and/or administration of a dialysate with higher potassium concentration may be necessary.
If hyperkalaemia occurs after treatment is initiated, additional sources of potassium influencing blood concentrations should be assessed. When the solution is used as a replacement solution, decrease the infusion rate and confirm that the desired potassium concentration is achieved. If hyperkalaemia does not resolve, stop the infusion promptly.

If hyperkalaemia develops when the solution is used as a dialysate, administration of a potassium-free dialysate may be necessary to increase the rate of potassium removal.

The inorganic phosphate concentration should be measured regularly. Inorganic phosphate must be substituted in cases of low level of phosphate in the blood. Phosphate up to 1.2 mmol/L may be added to the solution. If potassium phosphate is added, the total potassium concentration should not exceed 4 mEq/L (4 mmol/L).

Despite no cases of severe corn hypersensitivity reactions being reported with Prismasol, solutions containing glucose derived from hydrolysed maize starch should not be used in patients with a known allergy to maize or maize products.

The administration must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Because the solution contains glucose and lactate hyperglycaemia may develop, especially in diabetic patients. Blood glucose levels should be monitored regularly. If hyperglycaemia develops, administration of dextrose-free replacement solution/dialysate may be necessary. Other corrective measures may be needed to maintain desired glycaemic control.

Prismasol contains hydrogen carbonate (bicarbonate), and lactate (a hydrogen carbonate precursor) which can influence the patient's acid–base balance. If metabolic alkalosis develops or worsens during therapy with the solution, the administration rate may need to be decreased, or the administration stopped.

Before and during treatment, electrolyte and acid-base balance should be closely monitored throughout the procedure.

In case of fluid imbalance, the clinical situation must be carefully monitored and fluid balance should be corrected as needed.

Method of administration:
Intravenous use and for haemodialysis. Prismasol, when used as a substitution solution is administered into the circuit before (pre-dilution) or after the haemofilter (post-dilution).

Posology:
The volume and rate at which Prismasol is used will depend on the blood concentration of electrolytes, acid-base balance, and overall clinical condition of the patient. Administration (dose, infusion rate and cumulative volume) of Prismasol should be established by a physician.

Flow rates for the substitution solution in haemofiltration and haemodiafiltration are:
Adults: 500 - 3000 mL/h

Flow rates for the dialysis solution (dialysate) in continuous haemodialysis and continuous haemodiafiltration are:
Adults: 500 - 2500 mL/h

Commonly used flow rates in adults are approximately 2000 to 2500 ml/h which correspond to a daily fluid volume of approximately 48 to 60 L.

Paediatric population
The range of flow rates for the substitution solution in haemofiltration and haemodiafiltration and for the dialysis solution (dialysate) in continuous haemodialysis are:
Children (from neonates to adolescents to 18 years): 1000 to 2000 ml/h/1.73m².
Flow rates up to 4000 mL/h/1.73 m^2 may be needed, especially in younger children (≤10 kg). The absolute flow rate (in mL/h) in the paediatric population should generally not exceed the maximum adult flow rate.

Instructions for handling:
The electrolyte solution (small compartment A) is added to the buffer solution (large compartment B) after breaking the frangible pin immediately before use to obtain the reconstituted solution.

Use only with appropriate extracorporeal renal replacement equipment.

Aseptic technique should be used throughout the handling and administration to the patient.
Use only if the overwrap is undamaged, all seals are intact, frangible pin is not broken and the solution is clear. Press bag firmly to test for any leakage. If leakage is discovered, discard the solution

immediately since sterility can no longer be assured.

The large compartment B is fitted with an injection port for the possible addition of other necessary drugs after reconstitution of the solution. It is the responsibility of the physician to judge the compatibility of an additive medication with the Prismasol solution by checking for eventual colour change and/or eventual precipitation, insoluble complexes or crystals. Before adding a medication, verify if it is soluble and stable in water at the pH of Prismasol (pH of reconstituted solutions is 7.0 to 8.5). Additives may be incompatible. The Instructions for Use of the medication to be added must be consulted.
Remove any fluid from the injection port, hold the bag upside down, insert the drug through the injection port and mix thoroughly. The solution must be administered immediately. The introduction and mixing of additives must always be performed prior to connecting the solution bag to the extracorporeal circuit.

I Remove the overwrap from the bag immediately before use and discard any other packaging materials. Open the seal by breaking the frangible pin between the two compartments of the bag. The frangible pin will remain in the bag. (See figure I below)

II Make sure all the fluid from the small compartment A is transferred into the large compartment B. (See figure II below)

III Rinse the small compartment A **twice** by pressing the mixed solution back into the small compartment A and then back into the large compartment B. (See figure III below)

IV When the small compartment A is empty: shake the large compartment B so that the contents mix completely. The solution is now ready for use and the bag can be hung on the equipment. (See figure IV below)

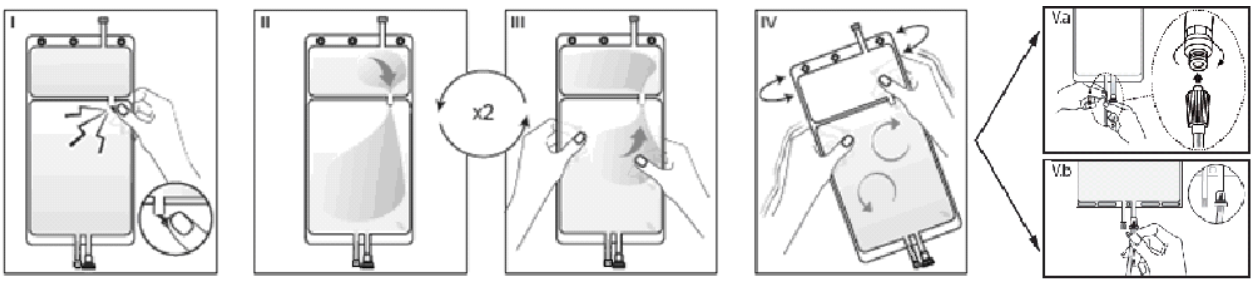
V The dialysis or replacement line may be connected to either of the two access ports.

V.a If the luer access is used, remove the cap with a twist and pull motion, and connect the male luer lock on the dialysis or replacement line to the female luer receptor on the bag using a push and twist motion. Ensure that the connection is fully seated and tighten. The connector is now open. Verify that the fluid is flowing freely. (See figure V.a below)
When the dialysis or replacement line is disconnected from the luer connector, the connector will close and the flow of the solution will stop. The luer port is a needle-less and swabbable port.

V.b If the injection port is used, first remove the snap-off cap. Then introduce the spike through the rubber septum. Verify that the fluid is flowing freely. (See figure V.b below)

The solution should be used immediately after removal of the overwrap. If not used immediately, the reconstituted solution should be used within 24 hours, including the duration of the treatment after addition of the electrolyte solution to the buffer solution.

The reconstituted solution is for single use only. Discard any unused solution immediately after use. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.



Package leaflet: information for the user

Prismasol 2 mmol/l Potassium Solution for haemodialysis/haemofiltration

Calcium chloride dihydrate/ magnesium chloride hexahydrate/ glucose monohydrate/ lactic acid solution 90% w/w / sodium chloride/ potassium chloride/ sodium hydrogen carbonate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Prismasol is and what it is used for

Prismasol contains the active substances calcium chloride dihydrate, magnesium chloride hexahydrate, glucose monohydrate, lactic acid solution 90% w/w, sodium chloride, potassium chloride and sodium hydrogen carbonate.

Prismasol is used in the treatment of renal failure as a solution for continuous haemofiltration or haemodiafiltration (as a replacement for fluid lost from the blood passing through a filter) and continuous haemodialysis or haemodiafiltration (the blood flows on one side of a dialysis membrane while a haemodialysis solution flows on the other side of the membrane).

Prismasol solution may also be used in case of drug poisoning with dialysable or filterable substances.

Prismasol 2 mmol/l Potassium is indicated particularly in patients who have tendency to hyperkalaemia (a high concentration of potassium in the blood).

2. What you need to know before you use Prismasol

Do not use Prismasol 2 mmol/l Potassium in case of:

- allergy to one of the active substances or any of the other ingredients (listed in section 6),
- a low concentration of potassium in your blood (hypokalaemia),
- a high concentration of bicarbonate in the blood (metabolic alkalosis).

Presence of corn antigen in Prismasol cannot be excluded.

Do not use haemofiltration/ dialysis in the following cases:

- Renal failure with pronounced hypercatabolism (abnormally increased catabolism), if the uraemic symptoms (symptoms caused by high concentration of urea in your blood) cannot be corrected with haemofiltration,
- Insufficient arterial pressure in the vascular access,
- Systemic anticoagulation (reduced clotting of your blood), if there is a high risk of haemorrhage (bleeding).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Prismasol.
The solution should be used only by, or under the direction of a doctor competent in renal failure treatments using haemofiltration, haemodiafiltration and continuous haemodialysis.

Before and during treatment, your blood condition will be checked, e.g. your acid-base balance and concentrations of electrolytes (salts in the blood) will be monitored, including all fluid you are given (intravenous infusion) and that you produce (urine production), even those not directly related to the therapy.
Your blood glucose concentration should be closely monitored, especially if you are diabetic.

Other medicines and Prismasol
Tell your doctor or pharmacist if you are given, have recently been given or might be given any other medicines.
The blood concentration of some of your other medicines may be reduced during the treatment. Your doctor will decide if your medication should be changed.

In particular tell your doctor if you are using either of the following:
- Digitalis medicine (for treatment of certain heart conditions) as the risk of cardiac arrhythmia (irregular or rapid beating of the heart) caused by digitalis is increased during hypokalaemia (low concentration of potassium in your blood).
- Vitamin D and medicinal products containing calcium, as they can increase the risk of hypercalcaemia (a high concentration of calcium in your blood).
- Any addition of sodium hydrogen carbonate (or other buffer source) may increase the risk of metabolic alkalosis (excess of bicarbonate in your blood).
- When citrate is used as an anticoagulant (as a protective additive in dialysis equipment), it can reduce plasma calcium levels.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if you should be given Prismasol if you are pregnant or breast-feeding.

Driving and using machines
Prismasol is not known to affect the ability to drive or use machines.

3. How to use Prismasol

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The volume of Prismasol used will depend on your clinical condition and the target fluid balance. The dose volume is therefore at the discretion of the responsible doctor.

Administration route: Intravenous use and for haemodialysis.

If you think you use more Prismasol than you should
Your fluid balance, electrolyte and acid-base balance will be carefully monitored.
In the unlikely event that an overdose occurs, your doctor will take necessary corrective measures and adjust your dose.
Overdose may result in:
- fluid overload in your blood,
- elevation of the bicarbonate blood level (metabolic alkalosis),

and/or reduction of levels of salts in the blood (hypophosphataemia, hypokalaemia).
Overdose could lead to severe consequences, such as congestive heart failure, electrolyte or acid-base disturbances.

For instructions for use, please see section “The following information is intended for healthcare

professionals only".

If you have any further questions on the use of this medicine, please ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

Not known: frequency cannot be estimated from the available data

- Changes of levels of salts in the blood (electrolyte imbalances such as hypophosphataemia, hypokalaemia)
- Elevation of the plasma bicarbonate concentration (metabolic alkalosis) or reduction of the plasma bicarbonate concentration (metabolic acidosis)
- Abnormally high or low volume of water in the body (hyper or hypovolemia)
- Abnormally high concentration of glucose in the blood (hyperglycaemia)
- Nausea
- Vomiting
- Muscle cramps
- Hypotension (low blood pressure).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via:

Malta:
ADR Reporting Website:
www.medicinesauthority.gov.mt/adrportal

Republic of Ireland:
HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

United Kingdom:
Yellow Card Scheme
www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prismasol

Keep this medicine out of the sight and reach of children.
Do not store below +4°C.
Do not use this medicine after the expiry date which is stated on the label and the packaging. The expiry date refers to the last day of that month.
Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 24 hours at +22° C. If not used immediately in-use storage times and conditions prior to use are the responsibility of the user and shall not be longer than 24 hours including the duration of the treatment.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prismasol contains

The active substances are:

Before reconstitution:
1000 ml of electrolyte solution (from the small compartment (A)) contains

Calcium chloride dihydrate	5.145 g
Magnesium chloride hexahydrate	2.033 g
Glucose	22.000 g
(S)-Lactic acid	5.400 g

1000 ml of buffer solution (from the large compartment (B)) contains

Sodium chloride	6.450 g
Sodium hydrogen carbonate	3.090 g
Potassium chloride	0.157 g

After reconstitution:
The solutions in the compartments A (250 ml) and B (4750 ml) are mixed to give one reconstituted solution (5000 ml) of which the composition is:

		mmol/l	**mEq/l**
Calcium	Ca^{2+}	1.75	3.50
Magnesium	Mg^{2+}	0.50	1.00
Sodium	Na^{+}	140.00	140.00
Chloride	Cl^{-}	111.50	111.50
Lactate		3.00	3.00
Hydrogen carbonate	HCO_3^{-}	32.00	32.00
Potassium	K^{+}	2.00	2.00
Glucose		6.10	
Theoretical Osmolarity:		297 mOsm/l	

The other ingredients are: carbon dioxide (E 290), water for injections
pH of the reconstituted solution: 7.0–8.5

What Prismasol looks like and contents of the pack

Prismasol is presented in a two-compartment bag containing in the smaller compartment A, the electrolyte solution, and in the larger compartment B, the buffer solution. The final reconstituted solution is obtained after breaking the frangible pin and mixing both solutions. The reconstituted solution is clear and slightly yellow. Each bag (A+B) contains 5000 ml solution for haemofiltration and haemodialysis. The bag is overwrapped with a transparent film.
Each box contains two bags and a package leaflet.

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This leaflet was last revised in 12/2020

The following information is intended for healthcare professionals only:

Prismasol 2 mmol/l Potassium Solution for haemodialysis/haemofiltration

Precautions:
The instructions for use / handling for Prismasol must be strictly followed.

The solutions in the two compartments **must be mixed before use**.
Use of contaminated haemofiltration and haemodialysis solution may cause sepsis, shock and fatal conditions.

Prismasol may be warmed to 37°C to enhance patient comfort. Warming of the solution prior to use should be done before reconstitution with dry heat only. Solutions should not be heated in water or in a microwave oven. The solution should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact.

The solution is a potassium-containing solution. The serum potassium concentration must be monitored before and during haemofiltration and/or haemodialysis. Depending on the serum potassium concentration before treatment, hypo- or hyperkalaemia may develop.
If hypokalaemia occurs, addition of potassium and/or administration of a dialysate with higher potassium concentration may be necessary.
If hyperkalaemia occurs after treatment is initiated, additional sources of potassium influencing blood concentrations should be assessed. When the solution is used as a replacement solution, decrease the infusion rate and confirm that the desired potassium concentration is achieved. If hyperkalaemia does not resolve, stop the infusion promptly.

If hyperkalaemia develops when the solution is used as a dialysate, administration of a potassium-free dialysate may be necessary to increase the rate of potassium removal.

The inorganic phosphate concentration should be measured regularly. Inorganic phosphate must be substituted in cases of low level of phosphate in the blood. Phosphate up to 1.2 mmol/L may be added to the solution. If potassium phosphate is added, the total potassium concentration should not exceed 4 mEq/L (4 mmol/L).

Despite no cases of severe corn hypersensitivity reactions being reported with Prismasol, solutions containing glucose derived from hydrolysed maize starch should not be used in patients with a known allergy to maize or maize products.

The administration must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Because the solution contains glucose and lactate hyperglycaemia may develop, especially in diabetic patients. Blood glucose levels should be monitored regularly. If hyperglycaemia develops, administration of dextrose-free replacement solution/dialysate may be necessary. Other corrective measures may be needed to maintain desired glycaemic control.

Prismasol contains hydrogen carbonate (bicarbonate), and lactate (a hydrogen carbonate precursor) which can influence the patient's acid–base balance. If metabolic alkalosis develops or worsens during therapy with the solution, the administration rate may need to be decreased, or the administration stopped.

Before and during treatment, electrolyte and acid-base balance should be closely monitored throughout the procedure.

In case of fluid imbalance, the clinical situation must be carefully monitored and fluid balance should be corrected as needed.

Method of administration:
Intravenous use and for haemodialysis. Prismasol, when used as a substitution solution is administered into the circuit before (pre-dilution) or after the haemofilter (post-dilution).

Posology:
The volume and rate at which Prismasol is used will depend on the blood concentration of electrolytes, acid-base balance, and overall clinical condition of the patient. Administration (dose, infusion rate and cumulative volume) of Prismasol should be established by a physician.

Flow rates for the substitution solution in haemofiltration and haemodiafiltration are:
Adults: 500 - 3000 mL/h

Flow rates for the dialysis solution (dialysate) in continuous haemodialysis and continuous haemodiafiltration are:
Adults: 500 - 2500 mL/h

Commonly used flow rates in adults are approximately 2000 to 2500 ml/h which correspond to a daily fluid volume of approximately 48 to 60 L.

Paediatric population
The range of flow rates for the substitution solution in haemofiltration and haemodiafiltration and for the dialysis solution (dialysate) in continuous haemodialysis are:
Children (from neonates to adolescents to 18 years): 1000 to 2000 ml/h/1.73m².
Flow rates up to 4000 mL/h/1.73 m^2 may be needed, especially in younger children (≤10 kg). The absolute flow rate (in mL/h) in the paediatric population should generally not exceed the maximum adult flow rate.

Instructions for handling:
The electrolyte solution (small compartment A) is added to the buffer solution (large compartment B) after breaking the frangible pin immediately before use to obtain the reconstituted solution.

Use only with appropriate extracorporeal renal replacement equipment.

Aseptic technique should be used throughout the handling and administration to the patient.
Use only if the overwrap is undamaged, all seals are intact, frangible pin is not broken and the solution is clear. Press bag firmly to test for any leakage. If leakage is discovered, discard the solution immediately since sterility can no longer be assured.

The large compartment B is fitted with an injection port for the possible addition of other necessary drugs after reconstitution of the solution. It is the responsibility of the physician to judge the compatibility of an additive medication with the Prismasol solution by checking for eventual colour change and/or eventual precipitation, insoluble complexes or crystals. Before adding a medication, verify if it is soluble and stable in water at the pH of Prismasol (pH of reconstituted solutions is 7.0 to 8.5). Additives may be incompatible. The Instructions for Use of the medication to be added must be consulted.
Remove any fluid from the injection port, hold the bag upside down, insert the drug through the injection port and mix thoroughly. The solution must be administered immediately. The introduction and mixing of additives must always be performed prior to connecting the solution bag to the extracorporeal circuit.

I Remove the overwrap from the bag immediately before use and discard any other packaging materials. Open the seal by breaking the frangible pin between the two compartments of the bag. The frangible pin will remain in the bag. (See figure I below)

II Make sure all the fluid from the small compartment A is transferred into the large compartment B. (See figure II below)

III Rinse the small compartment A **twice** by pressing the mixed solution back into the small compartment A and then back into the large compartment B. (See figure III below)

IV When the small compartment A is empty: shake the large compartment B so that the contents mix completely. The solution is now ready for use and the bag can be hung on the equipment. (See figure IV below)

V The dialysis or replacement line may be connected to either of the two access ports.

V.a If the luer access is used, remove the cap and connect the male luer lock on the dialysis or replacement line to the female luer receptor on the bag: tighten. Using thumb and fingers, break the blue frangible pin at its base, and move it back and forth. Do not use a tool. Verify that the pin is completely separated and that the fluid is flowing freely. The pin will remain in the luer port during the treatment. (See figure V.a below)

V.b If the injection port is used, first remove the snap-off cap. Then introduce the spike through the rubber septum. Verify that the fluid is flowing freely. (See figure V.b below)

The solution should be used immediately after removal of the overwrap. If not used immediately, the reconstituted solution should be used within 24 hours, including the duration of the treatment after addition of the electrolyte solution to the buffer solution.

The reconstituted solution is for single use only. Discard any unused solution immediately after use. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.